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10/575,122	04/07/2006	Ranga Madhavan Gurram	30251/09014 (fka DRF33028	9217
27530 7590 01/27/2010 Nelson Mullins Riley & Scarborough LLP			EXAMINER	
IP Department 100 North Tryon Street 42nd Floor			ZUCKER, PAUL A	
			ART UNIT	PAPER NUMBER
Charlotte, NC 28202-4000			1621	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Application No. Applicant(s) 10/575,122 GURRAM ET AL. Office Action Summary Examiner Art Unit Paul A. Zucker 1621 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 2a) ☐ This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-55.58 and 59 is/are pending in the application. 4a) Of the above claim(s) 56 and 57 is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) \_\_\_\_\_ is/are rejected 7) Claim(s) is/are objected to. 8) Claim(s) 1-55.58 and 59 are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date. Notice of Draftsperson's Patent Drawing Review (PTO-948)

Imformation Disclosure Statement(s) (PTC/S5/08)
 Paper No(s)/Mail Date \_\_\_\_\_\_.

Notice of Informal Patent Application

6) Other:

#### DETAILED ACTION

This application was filed 4/7/2006 and is a 371 of PCT/IB04/00208 (1/29/2004), which claims priority to International Bureau of the World Intell 03/04741 (10/28/2003). Claims 1-55 are before the Examiner. Claims 56-57 are not included in the below restriction requirement because they are drawn to non-statutory "Use of" subject matter.

### Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 14-36 and 41 (specifically) and claims 1-13,39-55 and 58-59 (generically) drawn to compounds, and compositions thereof, wherein Ar is phenyl and R1 and R2 are chains or non-hetero rings with an election of a single disclosed species.

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Group 2, claim(s) 1-13,39-40, 554-55 and 58-59 (generically) drawn to compounds, and compositions thereof, wherein R1 and R2 with the phenyl ring make

Group 3, claim(s) 1-13, 39-40, 54-55 and 58-59 (generically) drawn to compounds,

and compositions thereof, wherein R1 and R2 are

and H

- Group 4, claims 1-13, 39-40, 54-55 and 58-59 (generically) drawn to compounds, and compositions thereof, wherein Ar is phenyl and R1 and R2 are tricyclic non-heterocyclic ring with an election of a single disclosed species.
- Group 5, claims 1-13,39-40, 54-55 and 58-59 (generically) drawn to compounds, and compositions thereof, wherein Ar and R1 and R2 are other than encompassed by the above groups 1-4 with an election of a single disclosed species.
- Group 6, claim 37 drawn to processes for the preparation of compounds of formula

  (1). If Applicants elect this group, they are further required to elect a structural

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group from 1-5 above and a single specie of synthetic pathway for the transformation III (a-h)  $\rightarrow$  II (a-e)  $\rightarrow$ I to which examination will be restricted.

Group 7, claim 38 drawn to a process for the resolution of compounds of formula (I).

If Applicants elect this group, they are further required to elect a structural group from 1-5 above.

Group 8, claims 54, 55, 58 and 59, drawn to methods of treatment using compounds of formula (I). If Applicants elect this group, they are further required to elect a structural group from 1-5 above.

The inventions listed as Groups 1-8 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The special technical feature that all the groups have in common is the structure of general formula (I), as has been argued by Applicants. Formula (I) compounds, however, are not novel since Jeppeson et al (US 7,091,245-B2 08-2006) discloses (Column 33, lines 1-30) a compound of general formula (I). The special technical feature required for unity of invention is therefore not present.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

 No telephone call was made t to request an oral election to the above restriction requirement due to the complexity of the requirement.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does

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not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. <u>All</u> claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does

not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP \$ 804.01.

#### Conclusion

Claims 1-59 are pending. Claims 1-55, 58 and 59 are restricted. Claims 56 and 57
are held withdrawn from consideration as being drawn to non-statutory subject
matter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A. Zucker whose telephone number is 571-272-0650. The examiner can normally be reached on Monday-Friday 5:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Paul A. Zucker/ Primary Examiner, Art Unit 1621